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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEANNA LEWAKOWSKI, Individually and On Behalf of All Others Similarly Situated, Plaintiff, vs. AQUESTIVE THERAPEUTICS, INC., KEITH J. KENDALL, and JOHN T. MAXWELL, Defendants.	No.: 3:21-cv-03751-BRM-DEA **AMENDED CLASS ACTION COMPLAINT**

Lead Plaintiff Arthur Haase and Named Plaintiffs Matthew Smoak and Jamie Kakugawa ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Defendants (defined below), allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters.

I. INTRODUCTION

1. This is a class action brought on behalf of all persons who purchased Aquestive common stock between August 7, 2019 and September 25, 2020, both dates inclusive ("Class

Period"), and who were damaged thereby, pursuing remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder.[1]

2. Aquestive's future depends on a drug, Libervant, which uses the active pharmaceutical ingredient diazepam to treat epileptic cluster seizures. Aquestive seeks Libervant's FDA approval through a statutory provision that requires a showing that it is equivalent to the existing diazepam-based treatment, Diastat. At a meeting at which Aquestive argued that the studies it had conducted were sufficient to file Libervant's New Drug Application (NDA), the FDA asked Aquestive to conduct one last study measuring whether patients achieved the same diazepam blood concentration after receiving Libervant as after they received Diastat in real-world conditions. The results were troubling: 18% of patients reached peak bloodstream diazepam concentrations (a key metric) of only 50% as much under Libervant as they achieved under Diastat. This critical FDA-requested study called into question whether Libervant and Diastat were equivalent. But beginning August 2019, Defendants consistently and recklessly told investors that the study was an unqualified success and that there were no "low responders". In September 2020, Defendants announced that the FDA had rejected Libervant's NDA because 18% of patients were low responders. Aquestive's stock price fell by 34% in one day, damaging investors.

3. Defendants built Aquestive's business on a drug delivery system, PharmFilm, which is a strip patients can insert into their mouth to deliver a drug. Aquestive finds existing active pharmaceutical ingredients that are difficult for patients to use. Aquestive then creates a product that uses PharmFilm to deliver the ingredient and seeks FDA approval. By owning the

[1] Excluded from the Class are Defendants herein, Aquestive's officers and directors, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

products itself, rather than manufacturing PharmFilm for other companies, Aquestive keeps all the sale revenues.

4. The cornerstone of Aquestive's business plan was Libervant, a development-stage drug that would be used to treat potentially dangerous epileptic cluster seizures. The existing treatment, Diastat, is administered rectally. Aquestive proposed to deliver the same active pharmaceutical ingredient through the mouth with PharmFilm. Defendants told investors to expect $300 million in peak annual revenues, or about 4 times as much as Aquestive made in any year during the Class Period.

5. Defendants sought approval for Libervant through a particular statutory provision, Section 505(b)(2) of the Food, Drug, and Cosmetic Act. That provision lets companies rely on previous FDA findings that an existing drug that uses the same active pharmaceutical ingredient is safe and effective. But though applicants need not conduct full safety and effectiveness studies of their own, they must show that their drug is equivalent to the existing drug. If they fail, because they have not independently shown that their drug is safe and effective, the FDA will not approve it.

6. In December 2018, Defendants met with the FDA to determine what other trials to perform, if any, to complete Libervant's New Drug Application (NDA). As Defendants told investors, at that meeting the FDA required Aquestive to conduct just one more trial. The trial would compare Libervant against Diastat in the same patients in real-world conditions. Aquestive must show that the subjects achieved similar concentration of the active ingredient, diazepam, in their bloodstream after they received Libervant as after they received Diastat.

7. Defendants announced the results in August 2019. Then, and for the following year, Defendants repeatedly told investors the trial was an unqualified success. They told investors

specifically that no subjects were "low [Libervant] responders" in the trial. They told investors "every single time that we dose, in the studies that we've done, we've gotten the blood levels that we need in a clinical study." And they told investors they had met the FDA's specific requests for the additional study: "we believe we've provided the FDA with all of the appropriate data in response to the questions they had at our [December 2018] pre-NDA meeting."

8. Defendants used the false statements they made to raise $40.3 million they needed merely to survive 2020.

9. But Defendants misled investors. The trial was far from the unqualified success Defendants portrayed. In fact, as Defendants well knew, 18% of the subjects in that trial achieved only half as high peak bloodstream concentrations of diazepam after taking Libervant than they did after taking Diastat. The FDA might well reject Libervant, either because the study's findings affirmatively showed lack of safety or effectiveness or because they simply showed Libervant was not equivalent to Diastat.

10. It did. On September 25, 2020, Aquestive announced that it had received a letter from the FDA (called a Complete Response Letter, or CRL) stating that the FDA would not approve Libervant. According to Defendants, the FDA denied approval because 18% of patients achieved substantially lower peak bloodstream concentrations from Libervant than from Diastat – the very fact Defendants had misrepresented to investors.

11. The next trading day, Aquestive's stock price fell by 34%, damaging investors.

II. JURISDICTION AND VENUE

12. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

13. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

14. Venue is proper in this judicial district under §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as the alleged misstatements entered and the subsequent damages took place in this judicial district.

15. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

16. Lead Plaintiff Arthu Haase, as set forth in his previously-filed certification, which is incorporated by reference, purchased Aquestive securities at artificially inflated prices during the Class Period and was damaged thereby.

17. Plaintiffs Matthew Smoak and Jamie Kakugawa as set forth in their certifications attached hereto and incorporated by reference, purchased Aquestive securities at artificially inflated prices during the Class Period and was damaged thereby.

18. Aquestive historically received most of its sales revenues, and still does, from manufacturing PharmFilm strips for another company, Indivior, to use in its product, Suboxone. As Defendant Keith J. Kendall acknowledged, Aquestive's Suboxone business was "a melting ice cube," a declining business. So, before the Class Period, Aquestive began developing and seeking FDA approval of its own proprietary products which use PharmFilm as a delivery system for an active pharmaceutical ingredient. During the Class Period, Aquestive's shares traded on the NASDAQ.

19. Defendant Keith J. Kendall served as Aquestive's Chief Operating Officer from November 2011 through November 2014, and has served as its CEO and a Director of its Board since then.

20. Defendant John T. Maxwell served as Aquestive's CFO from January 2017 through December 2020.

21. Defendant Daniel Barber joined Aquestive in 2007. In 2009, he was promoted to Senior Director – Alliance Management, where he managed all of Aquestive's existing relationships. In particular, he led the team that helped launch Suboxone. In April 2014, Defendant Barber was promoted to SVP – Chief Strategy & Development Officer, a position he held until his promotion to Chief Operating Officer in April 2019.

22. Aquestive is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

23. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Aquestive under *respondeat superior* and agency principles.

24. Defendants Kendall, Maxwell, and Barber are the "Individual Defendants".

25. Aquestive and the Individual Defendants are the "Defendants".

IV. BACKGROUND

A. Aquestive's Suboxone Business Dies

26. Aquestive was founded in 2004 to sell products that use PharmFilm as a delivery system. Aquestive's first major success was Suboxone, marketed and sold by another company, Indivior Inc. and its parent Reckit Benckiser (collectively "Indivior").

27. Suboxone contains two active pharmaceutical ingredients, Buprenorphine and Naloxone. Buprenorphine is an opioid, while Naloxone substantially blocks the euphoria associated with opioids. Thus, Suboxone treats withdrawal symptoms while inhibiting the high that leads patients to abuse opioids. Further, it is difficult for patients to abuse Suboxone. If patients attempt to melt and inject Suboxone, the Naloxone will immediately cause the onset of withdrawal symptoms. Thus, unlike Methadone, which is usually physically provided to the patient on-site at a clinic, Suboxone is handed out to patients to use outside a clinic like any other prescription.

28. As alleged in an antitrust Complaint brought by 41 states and the District of Columbia ("State Suit"), Aquestive (then called MonoSol Rx, LLC) conspired with Indivior to prevent other companies from selling generic Suboxone even after Indivior lost exclusivity.[2]

29. Before it was sold as a film, Indivior sold Suboxone as a tablet. Aquestive and Indivior's scheme's goal was to shift the market to PharmFilm-based Suboxone before generic tablets could be sold.[3] Because the tablets are not substitutes for PharmFilm, pharmacies were not allowed to substitute generic tablets for suboxone PharmFilm prescriptions.[4] And because the film is protected by patents, while the tablets are not, convincing the market to accept the film and reject the tablets would de facto extend the Suboxone monopoly for more than a decade.

30. To further the scheme, Indivior:

a. Raised the price of tablets;

[2] *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4910673, at *3 (E.D. Pa. Oct. 30, 2017). While the complaint and memoranda of law in support of and in opposition to the defendants' motions to dismiss are sealed, the court set out the allegations in its Order denying Aquestive's motion to dismiss.
[3] *Id.* at *4.
[4] *Id.*

b. Created a patient subsidy program for the film, but provided no support for patients who took tablets;

c. Falsely told doctors and state healthcare systems that film was safer, in particular, they falsely stated it was safer in homes with children;

d. Paid its sales force to convert tablet sales to film.

31. After converting most of the market to film and just as generic tablets were due to enter the market, Indivior withdrew Suboxone tablets entirely from the market. Indivior raised alarms, claiming that it had discovered the tablets were not safe around children. This was not true. Indivior executives had invented the safety concerns. The film offered no advantage over the tablet to patients. In fact, it posed slightly higher risks to children.[5] The film only benefited Aquestive and Indivior because the films, unlike the tablets, were still patent protected.

32. The scheme doubly disadvantaged tablet manufacturers. First, patients had stopped using tablets. Second, the only company with experience selling suboxone tablets had claimed and was recounting to healthcare systems that the tablets were unsafe.

33. A report created by the former chief economist of the House Ways and Means Committee estimated that the scheme cost the U.S. healthcare system $403.2 million per year.[6]

34. The scheme originated with Aquestive. When it was founded, MonoSol advertised PharmFilm as "an ideal strategy for extending the life of a brand as generic incursion approaches." Another of MonoSol's slogans explained how it companies could use PharmFilm to defeat competition: "PharmFilm drug technology allows: no generic competition." ***MonoSol*** approached ***Indivior*** to propose the anticompetitive scheme. ***MonoSol*** attended Suboxone FDA meetings,

[5] *Id.* at *2.

[6] Alex Brill, The Cost of Brand Drug Hopping, September 2020, available for download at <https://www.affordableprescriptiondrugs.org/resources/the-cost-of-brand-product-hopping/>.

discussed Suboxone film pricing, negotiated an agreement that provided royalties from Suboxone sales, and applied for the Suboxone film patent on Indivior's behalf. ***MonoSol*** that suggested that Indivior withdraw Suboxone tablets from the market to harm generic competitors.[7] Defendant Maxwell admitted in a September 9, 2019, presentation at the H.C. Wainwright 21st Annual Investment Conference that ***MonoSol*** "helped Indivior create and get the product approved back in 2010, or leading up to 2010."

35. MonoSol and Indivior's conduct allowed them to charge higher prices to state and federal governments desperate to stem the suffering caused by the unfolding opioid catastrophe. But procured by crime, MonoSol's Suboxone business was unstable. An antitrust class action was filed in 2013, and a competitor sued in 2015. The State Suit was filed in 2016 after extensive discovery from both MonoSol and Indivior; it named MonoSol as a Defendant. Claims against Indivior and MonoSol substantially survived motions to dismiss in 2017. Generic tablets were approved for sale and acquired 40% of the market by the end of 2017. Indivior Inc. and Reckit Benckiser were criminally charged in April 2019. They pled guilty in 2020 and collectively paid $2 billion in fines. Indivior Inc.'s CEO pled guilty and was sentenced to six months in prison.

B. Aquestive Pivots To Developing Proprietary Products

36. It was clear well before the Class Period that MonoSol's Suboxone business was not sustainable. So beginning in 2015, Defendants shifted MonoSol's business to developing new proprietary drugs. They also changed its name to Aquestive to bury its past.

37. Aquestive would find drugs that were approved to treat conditions but which were difficult, invasive, or inconvenient for patients to use. Aquestive would then create products that

[7] *Suboxone*, 2017 WL 4910673, at *3.

used PharmFilm to deliver the same active pharmaceutical ingredient the drug used. Aquestive would then seek FDA approval to market the products.

38. By the time of its July 2018 IPO, Aquestive had already filed three New Drug Applications (NDA). But these drugs targeted limited markets. Aquestive's most promising drug was Libervant. Libervant targeted cluster seizures that afflicted hundreds of thousands of Americans.

39. Aquestive seeks approval of its product through a specific provision of the Food and Drug Act, 505(b)(2) (codified at 21 U.S.C. 355(b)(2)). A 505(b)(2) application relies, in part, on studies that were not conducted by the applicant. Because Aquestive aims to use PharmFilm to deliver active pharmaceutical ingredients that have already been approved, it can rely on the FDA's determination that the active pharmaceutical ingredients are safe and effective.

40. Aquestive need not and does not provide its own evidence that the active pharmaceutical ingredient is safe and effective. Aquestive thus avoids the usual thousand-plus patient clinical trials that cost hundreds of millions of dollars and take many years.

41. Instead, Aquestive need only conduct one or more bridging studies that demonstrate sufficient similarity between the applicant's product and the existing product to justify reliance on the existing product's scientific studies. Aquestive, like other applicants, must include sufficient information in its NDA to justify whatever differences exist between the two products. 21 CFR § 315.54(a).

42. Aquestive must establish equivalence at the individual subject level with a direct comparison of blood levels following Libervant exposure and following Diastat exposure.

C. Drug Manufacturers Race To Provide A More Practical Treatment For Cluster Seizures

43. Over 3.2 million Americans suffer from epilepsy. Every year, about 13% of these – 425,000 – experience cluster seizures, usually defined as 2 or 3 seizures occurring in one day.[8]

44. Typically, bouts of cluster seizures end on their own. But cluster seizures can lead to medical emergencies. The most dangerous side effect is status epilepticus, a long seizure (5 minutes or more) that might not stop without medical help. If not stopped within about 30 minutes, status epilepticus may cause permanent injury or death. More commonly, cluster seizures can lead to postictal psychosis, a psychotic episode. Postictal psychosis can leave patients with a range of psychotic symptoms, including hallucinations and disorders of thought. It usually lasts less than a week.

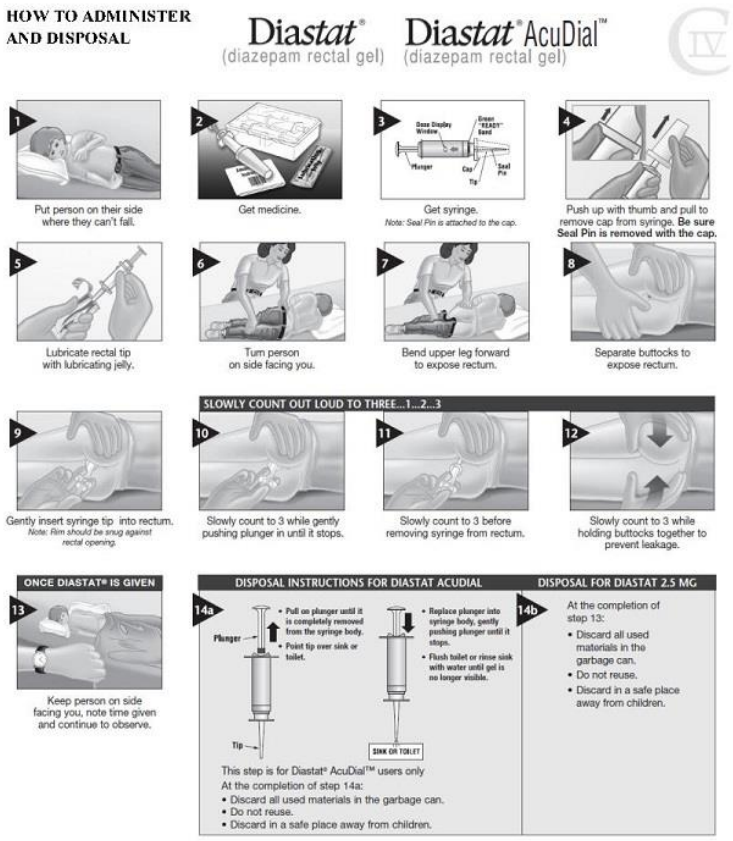
45. Most cluster seizures go away on their own. But some patients who begin a bout of cluster seizures resolve it in a hospital emergency room. There, a doctor or emergency technician injects the patient with diazepam, an active pharmaceutical ingredient known to halt seizure clusters. But an emergency room visit is a bad way to stop a treatable condition.

46. While there were many treatments that patients or their caregivers could themselves administer after the first seizure to prevent a cluster seizure, called rescue treatments, these treatments were all problematic. Until 2018, the only FDA-approved treatment for cluster seizures was Diastat. Diastat is a rectal gel. It must be applied by a caregiver (a close relative or a medical professional like a school nurse) trained to administer Diastat, not the patient him- or herself. It presents enormous social challenges for teens and adults. An adult might experience a cluster seizure outside the home, away from a close relative or caregiver or in a workplace without a

[8] Cluster seizures are also occasionally called Acute Repetitive Seizures, or ARS.

Diastat-trained medical professional. If the patient's cluster seizure emergency plan calls for application of Diastat, the patient can only wait for a caregiver to arrive. The patient must also find a private room in which the caregiver can apply Diastat. The patient, fearing stigma, may also be concerned that colleagues would wonder why the caregiver was necessary or what the caregiver was doing.

47. Diastat's label includes a chart giving instructions on its use. The chart shows how difficult, embarrassing, and potentially painful Diastat's application can be:



Reference ID: 4029527

48. Other patients take medications off label. By definition, these are medications that are approved only to treat another condition (not cluster seizures) and have not been shown to be effective in treating cluster seizures.

49. Diastat's deficiencies were no secret. At the beginning of the Class Period, manufacturers were racing to bring more practical treatments to the market. These included UCB S.A.'s Nayzilam, as well as three other products that use diazepam. One of these is Neurelis Inc.'s Valtoco, a convenient alternative taken intranasally that, despite Aquestive's best efforts to slow it down, was ahead of Aquestive in the race to bring an alternative to Diastat to the market.

D. Libervant Is By Far Aquestive's Most Important Drug

50. In the two months after Aquestive's July 2018 IPO, four analyst firms issued reports to their clients expressing an opinion about Aquestive. As is customary, the analysts put out price targets on Aquestive's stock, which are estimates of its value. The valuations all placed a premium on Libervant:

a. On August 20, 2018, an analyst employed by JMP Securities published a report on Aquestive. The JMP analyst's price target was $29/share. Of this, the JMP analyst attributed $12.50/share (43%) to Libervant, more than any other drug;

b. On August 20, 2018, an analyst employed by RBC Capital Markets published a report on Aquestive. The RBC analyst's price target was $23/share. Of this, the RBC analyst attributed $13/share (57%) to Libervant;

c. On August 20, 2018, an analyst employed by BMO Capital Markets published a report on Aquestive. The BMO analyst's price target was $26/share. The analyst did not value Aquestive's drugs individually. Instead, the analyst based his price target on a prediction of Aquestive's overall cash flows discounted by

time. According to the analyst, Libervant would account for four fifths of Aquestive's revenues in the period between 2020 and 2026. The analyst noted that he and his team were "[p]articularly bullish on Libervant for refractory seizures."

d. On September 12, 2018, an analyst employed by Wedbush securities published a report on Aquestive. The Wedbush analyst's price target was $33/share. Of this, the BMO analyst attributed $9.40/share (28%) to Libervant.

51. Defendants themselves told investors repeatedly during the Class Period that Libervant was critical to Aquestive's prospects. They told investors to expect peak annual sales of $300 million, or roughly 4 times Aquestive's peak annual Class Period sales.

52. Defendants also told investors their attention was focused on Libervant. On a November 6, 2019 call to discuss Aquestive's Q3 2019 earnings, Defendant Barber reiterated that "our focus right now [is] in Libervant and getting Libervant to the market and making sure we do all the things we need to do to be successful on that front." On a March 3, 2020 call to discuss Q4 2019 earnings call, Defendant Maxwell again confirmed that one of Aquestive's "two most important value drivers" was Libervant.

53. Tellingly, asked about the NDA submission status for another Aquestive product on a March 14, 2019 call, Defendant Barber erroneously began describing Libervant's status. After being corrected, Defendant Barber added "My apologies, [] I was giving you of Libervant. You can see where my mind is."

V. DEFENDANTS' FRAUDULENT CONDUCT

A. The FDA Instructs Aquestive to Test Libervant Against Diastat In Real-World Conditions

54. Aquestive began developing Libervant in or around early 2016.

55. The FDA designated Libervant an orphan drug in November 2016.

56. Aquestive began Libervant's first clinical trial in June 2017 and received interim results summer 2018.

57. Also in summer 2018, Aquestive presented the clinical trial's interim results and other clinical data to the FDA.

58. Defendants requested, and were granted, a pre-NDA meeting with the FDA to take place in December 2018.

59. Applicants use formal NDA meetings to have the FDA screen their applications to identify any deficiencies or additional studies they might conduct.

60. The meetings give applicants a chance to correct deficiencies before they lead to rejection.

61. It is expected that applicants will remedy any deficiency the FDA identifies. That is why applicants request FDA meetings.

62. At the December 2018 pre-NDA meeting, the FDA requested that Aquestive conduct an additional Libervant study.

63. While Libervant is administered buccally, it is absorbed by the body partially through the digestive track. Food may interfere with its absorption.

64. Comparing Libervant to Diastat in fasting patients may overstate Libervant's absorption into the bloodstream, called bioavailability.

65. In previously-conducted clinical trials, Aquestive had compared Libervant to Diastat in patients who had been fasting for 10 hours. In the real world, patients experiencing cluster seizures would rarely have gone that long without food.

66. The Crossover Study would compare differences in the absorption of diazepam in patients who had just eaten. Each patient would eat a medium-fat meal, and would then take either Diastat or Libervant. The concentration of diazepam in the patient's blood would be measured over the following hours and (much less frequently) days. The patient would wait 28 days and repeat the trial with the other product – i.e., if the patient had received Diastat the first time, the patient would receive Libervant the second time, and vice versa.[9]

67. One of the three metrics the trial measured was the highest concentration of diazepam the patient achieved following each of Libervant and Diastat, called Cmax.[10]

68. Aquestive compared each patient's Cmax after taking Libervant to the same patient's Cmax after taking Diastat. Aquestive thus determined the ratio of each patient's peak diazepam concentration after receiving Libervant as against after receiving Diastat. Defendants communicated the resulting ratio as a percentage. For example, if a patient's maximum peak diazepam concentration was half as much under Libervant as the same patient under Diastat, then that patient's Cmax ratio is 50%. Patient level Cmax ratios are critical and patient-level differences can cause the FDA to reject a new drug.

69. The Crossover Study aimed to show that the Cmax ratio was very close to 100% to establish that Libervant and Diastat are equivalent.

[9] If they wished, the patients could continue the trial by also taking Libervant after a high-fat meal.
[10] The other two were the time taken to reach Cmax (Tmax) and the Area-Under-Curve. The Area-Under-Curve takes into account both the concentration and the duration. To calculate the Area-Under-Curve, a chart plotting concentration over time is created. The Area-Under-Curve is the total area below the line showing concentration over time in the chart.

70. Only patients on anti-epileptic drugs ("AED") could participate in the study.

B. The FDA-Requested Clinical Trial Shows That Libervant May Not Be Equivalent To Diastat

71. Twenty-eight patients completed the Crossover Study. Of these, five (18%) achieved insufficient peak concentration when taking Libervant as compared to Diastat. These five patients on average achieved Cmax ratios of about 50%. In other words, 18% of patients reached peak concentrations under Libervant half as high as the concentrations they achieved under Diastat.

72. Libervant delivers emergency medication to treat potentially life-threatening conditions. The FDA may view that one sixth of patients who took Libervant achieved half the peak diazepam concentration than these same patients achieved after taking Diastat as evidence that Libervant does not work.

73. Further, to benefit from the FDA's finding that Diastat was safe and effective, Aquestive was required to show that Libervant was ***equivalent*** to Diastat. Because it sought approval under 505(b)(2), Aquestive did not need to, and did not, conduct studies to show that Libervant was safe and effective at the doses at which it would be prescribed. It did not supply the FDA with sufficient evidence of safety and effectiveness – deliberately – to let Libervant's application stand on its own. Thus, Libervant could not be approved without relying on the evidence that Diastat was effective at the doses at which it was prescribed. But because Libervant caused substantially different peak concentrations, the FDA could find that Libervant is not equivalent to Diastat – and hence, that there is not enough evidence that Libervant is safe and effective at the doses at which it would be prescribed. The evidence that Libervant and Diastat produce different peak blood concentration undermines Libervant's 505(b)(2) application even if it does not directly show or suggest that Libervant is unsafe or ineffective.

74. For these two reasons, the Protocol made clear that if there were any differences in Cmax between Libervant and Diastat, Aquestive would have to adjust the dose regimen:

> [I]t can be expected that diazepam Cmax values observed in this study following a moderate-fat meal will be similar under both treatments [i.e., Diastat and Libervant]. In the event that this is not the case***, Aquestive anticipates that results from this study will be used to refine the recommended dose regimen in consultation and collaboration with the [FDA]***.

75. Because of these two differences between the peak concentration patients achieved under Libervant as against under Diastat, Aquestive faced a substantial undisclosed risk that the FDA would find the Crossover Study was not successful.

76. And because the FDA had specifically requested the Crossover Study, any deficiencies in that study created substantial risks that the FDA would not approve Libervant.

C. Defendants Assure Investors That the FDA Scrutinized the Crossover Study[11]

77. On a November 6, 2018 call to discuss Libervant's NDA, Defendant Barber told investors that Aquestive had secured a pre-NDA meeting with the FDA:

> We are in ongoing dialog with the FDA regarding Libervant and recently received confirmation that we have been granted a face-to-face pre-NDA meeting for mid-December. At this meeting, we plan to share with the agency the data from our adult [Epilepsy Monitoring Unit Libervant] study, our population pharmacokinetics model, and the long term safety data that we have gathered to-date. The outcome of the pre-NDA meeting will then inform our submission strategy for Libervant. We are optimistic that the FDA will agree with the submission plan that we will present at this pre-NDA meeting.

78. Libervant's only remaining obstacle would be whatever additional study the FDA requested at the pre-NDA meeting, as Defendant Kendall stated:

> As [Defendant Barber] will elaborate shortly, we now have a pre-NDA meeting scheduled for mid-December, and the outcome of this meeting will inform our strategy and timing[.]

[11] The statements in this subsection are not themselves actionable, but they provide context to Defendants' actionable statements.

79. Then, on the December 20, 2018 call immediately after the pre-NDA meeting, Defendant Barber told investors that the FDA had largely "validated" Libervant's data:

> The [pre-NDA meeting] was a very positive meeting. ***There were a lot of elements of our program that were validated in that meeting, including the safety work we've done, including all of the PK work we've done to-date***.

80. To be prepared to file the NDA, Defendant Kendall said, Aquestive needed only to complete one additional study: "The one piece of PK bridging data we have not collected to date is Diastat data in patients under conditions of use. We will conduct a small, single-dose, crossover study versus our Libervant in order to obtain this data."

81. Defendant Barber assured investors that "***from our perspective, the FDA gave us verbal indication that we are very, very close and this is the end of the process.***"

82. Defendant Barber assured investors that the FDA would "review[] [Aquestive's] clinical synopsis and we're planning on submitting that synopsis for review today,"[12] and that it would prioritize the review:

> I think an example of [the FDA's desire to approve Aquestive] which we may not have stated so far is the FDA with a clinical synopsis would normally say, submit it through a formal process that takes quite a while to get review on. The head of the neurology division told us to send it directly to them so that they can rapidly review it and avoid the long formal process.

83. On Aquestive's next investor call on March 14, 2018, Defendant Kendall reiterated that the pre-NDA meeting's official minutes confirmed the impressions Defendants had conveyed to investors:

> We received our official meeting minutes from the FDA in mid-January. There were no surprises in the meeting minutes. And they were reflective of our understanding of the FDA's views coming out of the pre-NDA meeting.

[12] A synopsis is a summary of the Protocol.

84. Defendant Kendall added that "[a]s we previously communicated, we were prepared for this outcome and submitted a clinical study synopsis to the FDA immediately following our meeting in December. We received comments back from the FDA at the end of January[.]"

85. Defendants returned to the Crossover Study on a May 8, 2019 call to discuss Q1 2019 earnings. There, Defendant Barber claimed that the clinical trial would focus on comparing individual patients' responses to Libervant against their responses to Diastat:

> As I've shared with you in the past, following our pre-NDA meeting with the FDA last December, we initiated a crossover study that is designed to compare Libervant and Diastat in the same patient population and provide the final set of data to validate our dosing model. Our target enrollment in this study is 24 patients ***in order to obtain a complete pharmacokinetic data set on a minimum of 16 patients***.

86. On an August 7, 2019 call to announce the Crossover Study's results, Defendant Kendall stated that "in our discussions with FDA, ***we designed the protocol in consultation with them.***"

87. Thus, Defendants took pains to emphasize that the FDA had flyspecked the Crossover Study to give investors confidence that the Crossover Study addressed the FDA's concerns.

D. Defendants Falsely Assured Investors That the Crossover Study Had Met All Its Goals

88. On August 6, 2019, Defendants issued one press release announcing Q2 2019 financial results ("Q2 2019 PR") and another announcing the results of the Crossover Study ("Study Results PR").

89. In the Q2 2019 PR, Defendants stated:

> The Company reported positive topline data from the single dose crossover study, which compared the pharmacokinetic responses in a common set of

> patients receiving a dose of Libervant™ (diazepam) Buccal Film and a dose of diazepam rectal gel. Preliminary analyses show that the overall diazepam exposure achieved from the buccal film was the same as for gel based on the patient dosing algorithm and there was no difference between buccal film and gel in the effect of enzyme induction from taking concurrent anti-epileptic medications. ***Additionally, there were no instances of low or non-responders observed after Libervant administration***, while over 10% of those same patients failed to achieve adequate exposure following gel administration.

90. In the Study Results PR, Defendants stated:

> Among the 28 patients valid for analysis, three patients (10.7%) failed to achieve therapeutic concentrations of diazepam when using rectal gel. ***There were no such failures following buccal film administration.***

91. Then, on August 7, Defendants held a conference call to discuss both Q2 2019 earnings and the results of the Crossover Study. On the call, Defendant Kendall stated in prepared remarks:

> ***We believe that we've met the specific requirements for approval communicated to us by the FDA.***
>
> * * * * *
>
> ***Top line results confirmed our dosing model algorithm is appropriate for patients and will support a lower top dose than the top dose for the rectal gel. The results also show no difference between the film and the gel in patients using concurrent AED medications. In addition, once again, we observed several patients in the study who did not respond to a dose of the rectal gel, but in those same patients, we were able to produce therapeutic blood levels with Libervant.***

92. Defendants' emphasized statements in Paragraphs 88-91 were false and misleading because: (a) five of twenty-eight patients achieved peak concentration under Libervant that were only about 50% what they achieved under Diastat and, as a result, (i) there were "low responders" to Libervant, (ii) there were differences in overall diazepam exposure between Libervant and Diastat for patients on AEDs because all patients were on AEDs, (iii) these same five patients showed a "difference between the film and the gel in patients using concurrent AED medications",

and (iv) the concentration of diazepam was not relatively consistent between patients; (b) Defendants knew or were reckless in not knowing that Aquestive had not met the specific requirements the FDA communicated; and, as a result, (c) Defendants' statements gave the misleading impression that the Crossover Study had met all its goals.

93. On August 7, the price of Aquestive's stock closed at $3.52/share, up $0.37/share (11%) from its previous close of $3.15.

94. On September 9, 2019, Defendant Maxwell delivered a presentation at the H.C. Wainwright 21st Annual Investment Conference. One of the presentation's slides stated that the Crossover Study had shown that "***Diazepam exposure following buccal film showed comparable bioavailability to rectal gel as assessed by maximal plasma concentration (Cmax)***." The slide added that the Crossover Study "***confirmed [the] dosing algorithm***." Defendant Maxwell added in prepared remarks that "***every single time that we dose, in the studies that we've done, we've gotten the blood levels that we need in a clinical study.***"

95. Defendant Maxwell delivered the September 9 presentation as a representative and agent of Aquestive. In the September 9 presentation, Defendant Maxwell disclosed that "[Defendant] Kendall was going to be here, but he and I switched places last minute[.]" Because Defendant Kendall intended to deliver the presentation, he must have approved and/or drafted the presentation slides and prepared remarks that Maxwell delivered. So Defendant Kendall's scienter can be imputed to Aquestive in connection with both the slides Defendant Maxwell presented and his prepared remarks.

96. On November 5, 2019, Aquestive issued a Press Release announcing results for the third quarter of 2019 ("Q3 2019 PR"). The Q3 2019 PR provided:

> We ***successfully completed the crossover study*** requested by the U.S. Food and Drug Administration (FDA) for Libervant compared to the reference listed rectal gel.

97. On December 2, 2019, Aquestive issued a Press Release announcing the filing of Libervant's NDA, which quoted Defendant Kendall as saying:

> "We are very pleased to have completed our NDA filing for Libervant as we had committed. We look forward to sharing the results from the single dose crossover study at the upcoming American Epilepsy Society 2019 Annual Meeting. ***We believe these results confirm our dosing algorithm and satisfy the final clinical requirement requested by the FDA***[.]"

98. On December 9, 2019, Aquestive held a Forum and Webcast ("December 9 Presentation") to present the Libervant NDA to investors. One of the December 9 Presentation's purposes was laying the groundwork to raise funds off the back of the Libervant NDA the next week.

99. During the December 9 Presentation, Defendant Kendall stated that "***we're here to demonstrate why we believe we've provided the FDA with all of the appropriate data in response to the questions they had at our [December 2018] pre-NDA meeting***." Defendant Kendall added that "[a]t the end of the meeting today, I think you'll agree ***we have the data required for approval to bring this highly differentiated product, Libervant, to the market***[.]"

100. Defendants' emphasized statements in Paragraphs 94-99 were false and misleading because: (a) five of twenty-eight patients achieved peak concentration under Libervant that was only about 50% what they achieved under Diastat and, as a result: (i) Libervant's bioavailability was not comparable to Diastat's, (ii) Libervant's diazepam delivery was not "consistent and reliable", and (iii) Libervant did not achieve "the blood levels that we need" "every single time that [Aquestive] doses"; (b) Defendants either knew or were reckless in not knowing that Aquestive had not met the specific requirements the FDA communicated; and, as a result, (c)

Defendants' statements gave the misleading impression that the Crossover Study was an unqualified success.

101. Defendants' misleading statements achieved their goal. An August 6, 2019 report from JMP referred to the Crossover Study results as "the final de-risking event for the Libervant development program." An August 7, 2019 BMO report concluded that Libervant "Clear[ed] [its] Final Hurdle." Indeed, in a December 10, 2019 report, an analyst employed by Lake Street Capital Markets called Libervant's approval "A Black and White Answer in an Uncertain Space". The report added that "As Libervant is being approved through the 505(b)(2) regulatory pathway, it has to demonstrate equivalence to the reference drug, Diastat. ***This has been clearly established.***"

E. The FDA Finds That the Deficiencies in the Crossover Study Defendants Concealed Do In Fact Prevent Approval

102. On September 25, 2020, after close of trading, Defendants announced that Aquestive had received a Complete Response Letter (CRL) from the FDA, informing them that the FDA would not approve the Libervant NDA. As Defendants told investors that same day, the principal grounds cited by the FDA were that, as set out in ¶71-76, above, 18% of patients achieved an unacceptably low Cmax ratio.

103. On September 28, the next trading day, the share price of Aquestive's stock closed at $4.97, down $2.64 (34.6%) from its previous close of $7.61.

VI. ADDITIONAL FACTS FURTHER PROBATIVE OF SCIENTER

A. Pushing Forward With Libervant's NDA After the Crossover Study's Mixed Results Was Aquestive's Only Chance To Beat Its Competitor To Market

i. The Orphan Drug Act

104. The Orphan Drug Act provides incentives to develop treatments for, among other things, rare diseases. While the Orphan Drug Act offers tax breaks, the greatest benefit it offers is

orphan drug exclusivity. This exclusivity bars the FDA from approving any other drug using the same moiety (i.e., active pharmaceutical ingredient) for the same indication for seven years.

105. Orphan drug exclusivity is typically only available for conditions that have no approved treatment. But the FDA may grant exclusivity if a new drug provides "a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care." 21 USC § 360cc(c)(2). A "major contribution to patient care" can include a better method of administration. In determining whether a method of administration clears that bar, the FDA may consider: "convenient treatment location; duration of treatment; patient comfort; reduced treatment burden; advances in ease and comfort of drug administration; longer periods between doses; and potential for self-administration."[13]

106. Aquestive had obtained orphan drug designation for Libervant. But Neurelis Inc., a small private San Diego company, had received the same designation for its own product, Valtoco.

107. If Valtoco is approved first, Aquestive risks not being able to sell Libervant until 7 years later.

ii. Neurelis Builds A Substantial Lead In the Race to Approval

108. Neurelis Inc., a private San Diego drug company, was formed in 2007. According to a declaration under penalty of perjury signed by Neurelis CEO Craig Chambliss ("Chambliss Dec.") and filed in the action styled *Neurelis, Inc. v. Aquestive Therapeutics, Inc.*, Case No. 37-2019-646650CU-BT-CTL (Cal. Sup. Ct. San Diego), Neurelis was founded specifically to offer

[13]FDA, Frequently Asked Questions (FAQ) About Designating an Orphan Product, available at https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/frequently-asked-questions-faq-about-designating-orphan-product

patients experiencing cluster seizures a better option than Diastat. Chambliss Dec. ¶6. By 2008, Neurelis had developed a novel formulation for nasal delivery of diazepam that would become Valtoco.

109. In 2011, Neurelis conducted Valtoco's first human proof-of-concept study. *Id.* ¶ 9. Neurelis publicly announced the study's results in 2011.

110. In 2015, Neurelis announced that Valtoco had received an Orphan Drug Designation for management of cluster seizures. *Id.* ¶11.

111. In January 2016, Neurelis announced that it had initiated Valtoco's pivotal clinical trials. *Id.* ¶12.

112. As of July 2020, Neurelis had invested more than $100 million into Valtoco.

iii. Defendants Try To Buy Out Valtoco Before Aquestive's July 2018 IPO

113. In June 2017, Defendants Kendall and Barber asked Mr. Chambliss to meet in San Francisco, California. *Id.* ¶20.

114. At the meeting, Defendants Kendall and Barber told Mr. Chambliss they wanted to discuss the companies' diazepam programs purportedly to forge a strategic partnership between the two companies. *Id.*

115. Valtoco is taken intranasally, while Libervant is taken orally. In truth, Aquestive sought a meeting to halt or buy out Valtoco.

116. The meeting quickly fell apart. After learning that Aquestive had no experience with epilepsy, Mr. Chambliss explained to Defendants that Valtoco was taken intranasally and why the nasal method of administration was essential to the epilepsy community. Kendall interrupted Mr. Chambliss, stating: "Look, let's be honest here. We don't really care about the

patients, epilepsy, or any of this. We are not here for the patients, we are here for our investors and need to show them a return." *Id.* Soon after, Mr. Chambliss left the room. *Id.*

117. Kendall and Barber again asked to meet with Mr. Chambliss at the January 10, 2018 J.P. Morgan Healthcare Conference in San Francisco, California, to discuss a strategic partnership. *Id.* ¶ 22. Mr. Chambliss agreed to the meeting to discuss other products, having previously expressed interest in another program at Aquestive as a licensing opportunity. *Id.*

118. According to Mr. Chambliss, "[i]t quickly became clear to me during the meeting that Aquestive was only interested in gathering competitive intelligence on Neurelis and Valtoco." *Id.* ¶23.

119. At the meeting, Mr. Chambliss explained that Valtoco had completed or nearly completed its clinical trials and that its NDA filing was "impending". *Id.* ¶¶25, 26. Mr. Chambliss again told Defendants that Aquestive was not an appropriate partner for Neurelis on any matter, and again ended the meeting. *Id.* ¶23.

120. Though Chambliss told Defendants that Neurelis had no further interest in engaging with Aquestive for any purpose, on January 15, 2018, Defendant Kendall emailed Mr. Chambliss, telling him:

> We remain interested in a dialogue with Neurelis. We believe there is potential value to both companies and shareholder groups in the two working together in some fashion. As discussed "some fashion" is a very wide spectrum and we are willing to talk anywhere along that spectrum.

Id. Ex. 7.

iv. Defendants Threaten Litigation To Extort A Waiver of Valtoco's Impending Orphan Drug Exclusivity

121. In late 2018, Aquestive requested yet another meeting with Mr. Chambliss. The meeting would have taken place at the 2018 American Epilepsy Society Annual Meeting, taking place November 30-December 4, 2018. Mr. Chambliss refused. *Id.* ¶ 32.

122. On January 3, 2019, Defendant Barber conveyed through an intermediary that Aquestive was disappointed that Mr. Chambliss had turned down the meeting. *Id.* ¶ 33. The intermediary relayed another message from Aquestive: unless Mr. Chambliss agreed to meet Defendant Kendall at the January 9, 2019 J.P. Morgan Healthcare conference, Aquestive would file three Inter Partes Review requests with the Patent Trial and Appeal Board seeking to invalidate Neurelis's patent for the delivery system used in Valtoco. *Id.*[14]

123. Neurelis agreed meet. At the meeting, Defendant Kendall reiterated the threat to file three Inter Partes review requests against Neurelis's patents unless Neurelis agreed to "work together" with Aquestive. No agreement was reached. *Id.* ¶34.

124. Neither Neurelis nor Aquestive has ever contended that Aquestive infringes on Neurelis's patents. Valtoco's patent claims a method involving a "pharmaceutical solution for nasal administration", and Libervant is meant to be taken through the mouth.

125. Nor would invalidating Neurelis's patent benefit Aquestive. Orphan drug exclusivity is based on FDA regulations, not patents. So even if its patent were invalidated, Neurelis would still have 7 years' exclusivity.

[14] An Inter Partes Review request is a request made to the Patent Trial and Appeal Board to institute a trial-type proceeding challenging an already-issued patent. The only permissible grounds are that the existing patent was either non-obvious or not novel in light of patents and printed publications existing at the time the application was filed.

126. Thus, even if it won its patent case on all counts, Aquestive would reap no direct benefit. The litigation's only purpose was to extort concessions from Neurelis to avoid distraction, attorneys' fees, and the potential harm Neurelis could suffer if it sought to develop other products that employed the delivery system used in Valtoco. Defendant Kendall was threatening to spend the money investors had just provided him in Aquestive's IPO to pay for an extortion scheme.

127. On January 11, 2019, Chambliss and Aquestive attended a conference call to discuss Aquestive's threatened Inter Partes Review requests. On the call, Aquestive leadership offered to show Mr. Chambliss the contents of its Inter Partes review requests if Neurelis waived Orphan Drug Exclusivity. He declined. *Id.* ¶35.

128. Then on January 18, 2019, Defendant Kendall emailed a proposed agreement\ The Agreement claimed that the waiver of orphan drug exclusivity would be in aid of an undefined "potential business transaction", though none had been discussed and Neurelis had no interest in any transaction. The agreement's filename ("Agreement Neurelis Waiver.doc") told the true story: Defendants were using the threat of litigation to extort a concession.

129. Defendant Kendall threatened that unless Neurelis signed the agreement by the following Monday the 21st, Aquestive would file the Inter Partes Review petitions. *Id.* ¶38 & Ex. 10.

130. Neurelis declined, and Aquestive filed its Inter Partes Review petitions.

v. Aquestive Files A Frivolous Citizen's Petition To Delay Valtoco's Entry

131. Having failed to extort a concession, Aquestive turned to abuse of process. On November 1, 2019, Aquestive filed a citizen petition ("Citizen Petition") with the FDA seeking that it stay approval of Valtoco until Neurelis completed an additional study.

132. A citizen petition may be filed with the FDA to ask it to take or refrain from taking an administrative action. 21 C.F.R. § 10.30. It is intended to be used to raise concerns about the safety or legality of a product. The FDA has 150 days to respond and, because the FDA typically does not take the action requested during the period in which it is considering the petition, citizen petitions are sometimes abused by manufacturers to delay a competitor's approval for tactical reasons.

133. To further Aquestive and Indivior's scheme to maintain a Suboxone monopoly, Indivior had filed a sham citizen petition seeking to delay approval of generic tablets. The Suboxone citizen petition asked the FDA not to approve the generics until the FDA had thoroughly investigated the safety concerns that Indivior had invented out of whole cloth.[15] That meritless citizen petition delayed approval by almost six months. The FDA referred the citizen petition to the Federal Trade Commission to determine whether its filing was anticompetitive. Aquestive "actively participated in this process, holding 'urgent' meetings with Indivior to explore possible citizen petition opportunities regarding Suboxone tablets."[16]

134. The FDA denied the Citizen Petition on January 10, 2020, the same day it approved Valtoco. In its denial, the FDA noted that the Citizen Petition was filed when it was considering Valtoco's approval. The FDA concluded that the Citizen Petition had likely been filed merely to delay Valtoco's approval rather than to raise substantive concerns. FDA Denial at 2 n.2.

vi. Defendants Risked Losing the Race to Approval If They Sought Clarification From the FDA

135. Defendants received and announced the Crossover Study Results in August 2019. While they did not know when the FDA would determine whether to approve Valtoco, they knew

[15] *Suboxone*, 2017 WL 4910673, at *4 (E.D. Pa. Oct. 30, 2017).
[16] *Id.*

Neurelis had announced the filing of Valtoco's NDA in September 2018, while Aquestive planned to complete the filing of its NDA in Q4 2019.

136. With Valtoco nearing its approval decision, Defendants had no time to seek clarification from the FDA. Defendants would first have to seek a meeting from the FDA. Even if the FDA agreed to the meeting, it would not be held for months, while Aquestive would have to wait more months for the minutes. And if the FDA clarified that Aquestive needed to do further work, which is why Aquestive would request the meeting in the first place, then Aquestive could not hope to file for at least six months. Indeed, when the FDA rejected Libervant in September 2020, Aquestive did not refile until June 24, 2021.

B. Defendants Needed Cash They Could Only Secure By Selling Stock

137. Before the Class Period, Aquestive earned a substantial majority of its sales revenues from selling PharmFilm as a delivery system for suboxone. During the year ended December 31, 2017, Aquestive earned 88% of its revenues from these suboxone-related sales, rising to 97% for the quarter ended March 31, 2018.

138. As Defendant Kendall explained at the RBC Capital Markets Conference on May 19, 2021, "we've often referred to suboxone as a melting ice cube." That is in part because, as further alleged above, Aquestive and Indivior could no longer hold Suboxone generic manufacturers at bay through anticompetitive tactics.

139. More, multiple generic manufacturers had filed Abbreviated New Drug Applications ("ANDA") with the FDA, maintaining that their product either did not infringe the PharmFilm patent or that the patent itself was invalid. On November 20, 2018, the United States Court of Appeals for the Federal Circuit preliminarily found that one competitor's suboxone film

did not infringe Aquestive's patent, vacating a preliminary injunction that had prevented sale of the competitor's product.

140. Thus, from the very beginning of the Class Period, Aquestive's primary source of revenues was bound to disappear. And indeed, Aquestive's manufacturing revenues tumbled even as it introduced new products:

Year ended December 31:	Manufacturing and supply revenue
2017	$40.1 million
2018	$37.3 million
2019	$38.7 million
2020	$24.9 million

141. Aquestive had to develop new funding sources to support its clinical programs. On a call to discuss Aquestive's Q4 2018 earnings, Defendant Maxwell boasted that Aquestive had many options to avoid having to sell its stock:

> [W]e will be looking, as we've said before, at our different capital options. Given the apomorphine delay, and we still don't know the timing on that yet, we made the decision to focus first on the financing – refinancing of our debt. That comes due in 2020. But we can move to 2019 to refinance. We will explore the options. We think there's potentially additional amount of little capital that we can get out of that. In addition to that, we think that it is – there will be savings in terms of principal repayment as well. So that's a cash positive. Then when we think about other options in front of us before we get to equity, you've got the apomorphine milestone under the apomorphine deal that we could do.

142. Defendant Maxwell maintained that it made no economic sense for Aquestive to fund its operations by selling stock, continuing:

> ***The cost of capital is too high to [sell stock] before [Libervant] approval. So we prefer to wait until after the approval.***

143. At the time, Aquestive's stock was trading for about $6.50 per share.

144. Yet in December 2019, weeks after it announced that it had filed for Libervant's approval, Aquestive sold 8.05 million shares at a price of $5.00 each in an underwritten offering, raising $40.3 million in gross proceeds. Given Defendants' comment that Aquestive would avoid selling stock if it could, Aquestive had plainly exhausted all other sources of funds.

C. Aquestive Made Impossible Promises About Libervant's Approval

145. The FDA has 60 days to decide whether to accept an NDA filing. The FDA then must still determine whether to approve the filing. The FDA takes approximately eight to ten months to reach a decision.

146. Thus, Aquestive's best case for Libervant was approval within ten months of filing.

147. Defendants delivered a confidential webinar to investors at the BMO Conference on October 10, 2017. In the presentation, Defendants told investors to expect approval of Libervant in Q4 2018.

148. To meet this goal, Aquestive would have to file Libervant's NDA in or around January 2018

149. Aquestive began two Phase 2 Libervant clinical trials in summer 2017. The institutions that would conduct the trials did not agree to do so until November 10, 2017. [17]

150. Before filing the Libervant NDA, Aquestive would have to hold a pre-NDA meeting (among others) with the FDA.

[17]Study to Assess the Pharmacokinetics and Safety of DBSF in Adult Subjects With Epilepsy, November 10, 2017 update, available at https://clinicaltrials.gov/ct2/history/NCT03179891?V_4=View#StudyPageTop; Assessment of Pharmacokinetics and Safety of Diazepam Buccal Soluble Film in Pediatric Patients (DBSF), November 10, 2017, available at https://clinicaltrials.gov/ct2/history/NCT03222349?V_3=View#StudyPageTop

151. With no clinical program to speak of and lengthy delays in approval, Defendants could not hope to secure FDA approval of Libervant in 2018. Defendants lied to investors then, too.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

152. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the publicly traded securities of Aquestive during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, Aquestive's officers and directors, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

153. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Aquestive or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

154. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

155. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

156. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants' acts as alleged violated the federal securities laws;

(b) whether Defendants' statements to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of Aquestive;

(c) whether Defendants' statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether the Individual Defendants caused Aquestive to issue false and misleading SEC filings and public statements during the Class Period;

(e) whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;

(f) whether the prices of Aquestive's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(g) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

157. Common questions of law and fact predominate over any questions affecting only individual Class members. Because the common stock of Aquestive traded in an efficient market

and Defendants' false and misleading statements had impacted the price of Aquestive common stock, Plaintiffs will establish reliance for themselves and the Class through the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's securities are traded in an efficient market;

(d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company traded on the NASDAQ, and was covered by many analysts;

(f) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; Plaintiffs and members of the Class purchased and/or sold the Company's securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and

(g) Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

158. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market, establishing predominance.

159. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material

information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

160. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

NO SAFE HARBOR

161. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

COUNT I
Violation of Section 10(b) of The Exchange Act and Rule 10b-5
Against All Defendants

162. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

163. Plaintiffs assert this claim against all Defendants, basing the claim upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

164. During the Class Period, in violation of Section 10(b) of the Exchange Act and Rule 10b-5(b), the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations, omitted material facts, and failed to disclose material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading.

165. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5(a) and (c) in that they employed devices, schemes and artifices to defraud and/or engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Aquestive's securities and directly impacted the price of Aquestive's common stock during the Class Period.

166. The Company and the Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated in Aquestive's name were materially false and misleading and omitted material information; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly or recklessly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants, by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements or material omissions, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein. Information showing that Aquestive, by and through the Individual Defendants, and other senior Aquestive officers and

employees, acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control.

167. The Individual Defendants knew or recklessly disregarded the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Aquestive personnel to members of the investing public, including Plaintiffs and the Class.

168. As a direct and proximate result of the scheme or artifice to defraud that lead directly to Aquestive's disclosing materially false and misleading information, the market price of Aquestive's securities was artificially inflated during the Class Period. In ignorance of the falsity of the statements at issue, Plaintiffs and the other members of the Class relied on the statements described above and/or on the integrity of the market price of Aquestive's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of Aquestive's false and misleading statements and omissions.

169. Had Plaintiffs and the other members of the Class been aware that the market price of Aquestive's securities had been artificially and falsely inflated by the fraudulent scheme that caused Aquestive to issue misleading financial statements, and by the material adverse information which the Company did not disclose, causing artificial inflation in Aquestive's stock price, they would not have purchased Aquestive's securities at the artificially inflated prices that they did, or at all.

170. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

171. By reason of the foregoing, Defendants Aquestive and the Individual Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchases of Aquestive's securities during the Class Period.

COUNT II
Violation of Section 20(a) of the Exchange Act
Against the Individual Defendants

172. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

173. During the Class Period, Aquestive, by and through its officers and directors, violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

174. The Individual Defendants participated in the operation and management of Aquestive and its operating units, and conducted and participated, directly and indirectly, in the conduct of Aquestive's business affairs. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Aquestive's financial condition and results of operations, and to correct promptly any public statements issued by Aquestive which had become materially false or misleading.

175. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Aquestive disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority over Aquestive. The Individual Defendants, therefore, were "controlling persons" of Aquestive within

the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Aquestive's securities.

176. Each of the Individual Defendants, therefore, acted as a controlling person of Aquestive. By reason of their senior management positions and/or being directors of Aquestive, each of the Individual Defendants had the power to direct the actions of, and exercised the same, to cause Aquestive to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Aquestive and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

177. By reason of the foregoing, the Individual Defendants have violated Section 20(a) of the Exchange Act and are jointly and severally liable to the Plaintiffs and the other members of the Class for substantial damages that they suffered in connection with their purchases of Aquestive's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, certifying Plaintiffs as Class Representatives, and approving Lead Counsel and Local Counsel as counsel to the Class;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

Dated: June 25, 2021

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

/s/ Laurence M. Rosen
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THE ROSEN LAW FIRM, P.A.

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Fax: (212) 202-3827

Lead Counsel for Plaintiffs

CERTIFICATION

Jamie Kakugawa ("Plaintiff") authorizes The Rosen Law Firm, P.A. to file an action or amend a current action under the federal securities laws to recover damages and to seek other relief against Aquestive Therapeutics, Inc. ("Aquestive"), and its current and/or former officers.

Plaintiff declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff has reviewed a complaint against Aquestive and retained The Rosen Law Firm, P.A.

2. Plaintiff did not engage in transactions in the securities that are the subject of this action at the direction of Plaintiff's counsel or in order to participate in this or any other litigation under the securities laws of the United States.

3. Plaintiff is willing to serve as a lead plaintiff either individually or as part of a group. A lead plaintiff is a representative party who acts on behalf of other class members in directing the action, and whose duties may include testifying at deposition and trial.

4. The following is a list of all of the purchases and sales Plaintiff has made in Aquestive securities during the Class Period set forth in the complaint. Plaintiff has made no transactions during the Class Period in the securities that are the subject of this lawsuit except those set forth here:

See Schedule A

5. Plaintiff has not, within the three years preceding the date of this certification, sought to serve or served as a representative party on behalf of a class in an action involving alleged violations of the federal securities laws, except: for the following company(ies):

6. Plaintiff will not accept any payment for serving as a representative party beyond his pro rata share of any recovery, except reasonable costs and expenses, such as travel expenses and lost wages directly related to the class representation, as ordered or approved by the court pursuant to law.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 6/18/2021

DocuSigned by:
EE7A1BD4F8AD420...

Jamie Kakugawa

SCHEDULE A

JAMIE KAKUGAWA

CLASS PERIOD TRANSACTIONS

PURCHASES

DATE	SHARES	PRICE
12/9/2019	1	($8.08)
12/11/2019	7	($6.75)

CERTIFICATION

Matthew Smoak ("Plaintiff") authorizes The Rosen Law Firm, P.A. to file an action or amend a current action under the federal securities laws to recover damages and to seek other relief against Aquestive Therapeutics, Inc. ("Aquestive"), and its current and/or former officers.

Plaintiff declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff has reviewed a complaint against Aquestive and retained The Rosen Law Firm, P.A.

2. Plaintiff did not engage in transactions in the securities that are the subject of this action at the direction of Plaintiff's counsel or in order to participate in this or any other litigation under the securities laws of the United States.

3. Plaintiff is willing to serve as a lead plaintiff either individually or as part of a group. A lead plaintiff is a representative party who acts on behalf of other class members in directing the action, and whose duties may include testifying at deposition and trial.

4. The following is a list of all of the purchases and sales Plaintiff has made in Aquestive securities during the Class Period set forth in the complaint. Plaintiff has made no transactions during the Class Period in the securities that are the subject of this lawsuit except those set forth here:

See Schedule A

5. Plaintiff has not, within the three years preceding the date of this certification, sought to serve or served as a representative party on behalf of a class in an action involving alleged violations of the federal securities laws, except: for the following company(ies):

6. Plaintiff will not accept any payment for serving as a representative party beyond his pro rata share of any recovery, except reasonable costs and expenses, such as travel expenses and lost wages directly related to the class representation, as ordered or approved by the court pursuant to law.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 6/25/2021

DocuSigned by:
Matthew Smoak
6182758D91534C7...

Matthew Smoak

SCHEDULE A

MATTHEW SMOAK

CLASS PERIOD TRANSACTIONS

PURCHASES

DATE	SHARES	PRICE
12/02/2019	10	($8.55)
12/02/2019	1	($8.55)